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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,323	10/27/2000	Jeffrey M. Isner	47624-DIV (1417)	6299
21874 75	590 12/09/2003		EXAMINER	
EDWARDS & P.O. BOX 9169	& ANGELL, LLP		NGUYEN, QUANG	
BOSTON, MA 02209			ART UNIT	PAPER NUMBER
			1636	
			DATE MAILED: 12/09/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

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## **Advisory Action**

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Application No.	Applicant(s)	
09/698,323	ISNER ET AL.	
Examiner	Art Unit	· · · · · · · · · · · · · · · · · · ·
Quang Nguyen, Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.
PERIOD FOR REPLY [check either a) or b)]
a) $\square$ The period for reply expires $\underline{5}$ months from the mailing date of the final rejection.
b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).
Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).
1. A Notice of Appeal was filed on <u>20 October 2003</u> . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. The proposed amendment(s) will not be entered because:
(a) ☑ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) they raise the issue of new matter (see Note below);
(c) \( \sum \) they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) they present additional claims without canceling a corresponding number of finally rejected claims.
NOTE: <u>See Continuation Sheet</u> .
3. Applicant's reply has overcome the following rejection(s):
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed:
Claim(s) objected to:
Claim(s) rejected: <u>50,52,55-63,65-68,70 and 72-81</u> .
Claim(s) withdrawn from consideration:
8. The drawing correction filed on is a) approved or b) disapproved by the Examiner.
9. Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s)
10. Other:
David Juso
and the state of the

U.S. Patent and Trademark Office PTOL-303 (Rev. 11-03) Continuation Sheet (PTOL-303) 009/698,323

Application No.

Continuation of 2. NOTE: The limitation "wherein the mammal is a rodent or a primate" in the newly amended claim 50 raises new issues, that would require further consideration, particularly 112, first paragraph. For example, as enablement requires the specification to teach how to make and use the claimed invention, in this instance it is not entirely clear what is the use for treating (inducing formation of new blood vessels) specifically a rodent or a non-human primate having chronic or acute ischemia.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments are based on the entry of the proposed amendments which are not entered for the reasons set forth above.

Assuming that the proposed amendments to be entered, with respect to the rejection under 35 U.S.C. 103 by Hammond et al. in view of Asahara et al. or Isner et al., Applicants submitted the Declaration under 37 CFR 1.131 to antedate the Hammond reference. The rejection is maintained because:

- (1) The Declaration is unsigned.
- (2) The Declaration is not commensurate with the scope of the proposed claims. While the Declaration showed that Applicants induced formation of new blood vessels in mice and rabbits using granulocyte-macrophage colony stimulating factor (GM-CSF) prior to 9/19/1997, there is no evidence that Applicants induced formation of new blood vessels in any primate using GM-CSF, let alone a host of hematopoietic factors such as SCF, SDF-1, G-CSF, M-CSF, angiopoietin-1, angiopoietin-2, FLT-3 ligand as encompassed by the proposed claims.

The proposed amendment would overcome the rejection under 35 U.S.C. 102(b) by Takeshita et al.